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Nevada State Board of Pharmacy

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Board Members

Lunch Anyone?

Nevada Revised Statute 608.019(1) requires employers to permit employees who work continuous periods of eight or more hours to have an uninterrupted meal period of at least one-half hour. Until recently, said "uninterrupted meal period" has never been addressed in our statutes or regulations. In December 2005, the Nevada State Board of Pharmacy passed regulations that permit all employees of a pharmacy, including pharmacists, to take a meal period if they so desire. Judging from the many calls to the Board office, confusion exists among you. Here are the simplified rules:

1. The owner of a pharmacy shall permit each employee of the pharmacy to take meal periods and rest periods (30 minutes/8 hours for meals and 10 minutes/4 hours for rest).
2. If there is more than one pharmacist on duty at the time of the meal period, the pharmacist may eat either on or off the premises.
3. If the pharmacist is the only one on duty at the time of the meal period, he or she may, at his or her discretion, eat in the pharmacy (and be interrupted or not at his or her option) or leave the pharmacy, provided he or she closes and secures the pharmacy (everyone out) and posts a sign visible to the public stating the time of his or her return.
4. A pharmacy closed and secured during a meal period may accept a prescription by an authorized employee outside the pharmacy or by a secure container or receptacle that would meet Health Insurance Portability and Accountability Act privacy requirements.

Note: the Board did not address the issue of pay, or lack thereof, during a meal period.

Fraudulent Prescriptions

Interestingly, the Controlled Substance Abuse Task Force often receives calls from pharmacists questioning whether or not the prescription they **just filled** was fraudulent (and often it is). It seems that the prudent move would be to ask that question **prior** to sending the drugs out the door. As a reminder, to verify a Drug Enforcement Administration (DEA) number, calculate as follows:

- Add the first, third, and fifth numbers to get your first number.
- Add the second, fourth, and sixth numbers and multiply by two to get your second number.
- Total the two numbers and the last digit of this number will be the same as the last digit of the DEA number.

Continuing Education Requirements

The recent audit of pharmacists' continuing education (CE) resulted in higher compliance than past audits. It also illustrated some issues that need clarification. The following summarizes reasons for audited pharmacists failing to meet CE requirements:

Failed to complete CE units (CEUs) within the required time period:

Any certificates dated before November 1, 2003, or after October 31, 2005, were not eligible for credit.

Failed to complete one CEU in a jurisprudence program approved by the Board:

This requirement can be met by attending a Nevada law program presented by Board staff or by attending at least four hours of a Board meeting.

Note – Accreditation Council for Pharmacy Education

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FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben®, a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien®, a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Problem: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis. An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a $175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working

with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- A table of contents for easy reference to detailed safety and efficacy information.
- The date of initial product approval, making it easier to determine how long a product has been on the market.
- A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

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(ACPE)-accredited pharmacy law related programs do not count toward this requirement unless they are approved by the Board for this purpose.

Failed to complete 15 CEUs in accredited programs:

Accredited programs are those accredited by ACPE or by the Nevada Board of Pharmacy only.

Failed to provide copies of CE certificates:

Summaries of programs from providers are not acceptable. You must provide copies of certificates from the provider that includes:

- Your name;
- Name of the provider;
- Hours or units of credit;
- Date of completion; and
- Signature of a representative of the provider.

The Board office does not have copies of law CE certificates. If you are audited and you do not have your certificate, you will need to obtain a duplicate for the provider.

Be advised: Upon signing your renewal form or submitting your renewal online, you are certifying under penalty of perjury that you have completed all CE requirements for the renewal of your Nevada pharmacist license.

On the Subject of CE, How About CE for Pharmacy Technicians?

Pharmacy technicians are not required by law to have CE. Nevada Administrative Code 639.254 requires "in-service training" rather than CE for competency to perform the functions of their employment. This training (12 hours per renewal period) must be documented by the managing pharmacist in a record to be made available to Board inspectors upon request. Even though law does not mandate that pharmacy technicians require CE, the Board of Pharmacy would like to encourage all technicians to partake in CE and especially a law CE. Pharmacy practice laws and regulations are continuously evolving. Given the intricate role that pharmacy technicians serve in our drug delivery system, a thorough understanding of the law would increase efficiency in pharmacy operations.

Topamax/Toprol-XL

Based on a review of spontaneous reports submitted to Food and Drug Administration, the World Health Organization, and the United States Pharmocopeia, prescriptions for Topamax® (topiramate) and Toprol-XL® (metoprolol succinate) have been incorrectly written, interpreted, labeled, and/or dispensed. Possible explanations for these errors include similarity in names, proximity of the two products on the shelf, proximity in computer listings, and similar dosage strengths. Board staff urges you to pay particular attention when verifying and dispensing oral and written prescriptions for these two medications. Two other sets of medications that should be on your radar are Seroquel®/Serzone® and Roxinal®/Roxicet®. This is another illustration of the importance of counseling.

The *Nevada State Board of Pharmacy News* is published by the Nevada State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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